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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/966,511      | 09/28/2001  | Deral T. Mosbey      | 55837US002          | 4740             |

32692 7590 07/14/2003

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EXAMINER

WELLS, LAUREN Q

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                       |                 |
|------------------------------|-----------------------|-----------------|
| <b>Office Action Summary</b> | <b>Applicant(s)</b>   |                 |
|                              | MOSBEY ET AL.         |                 |
|                              | <b>Application N°</b> | <b>Art Unit</b> |
|                              | 09/966,511            | 1617            |
|                              | <b>Examiner</b>       |                 |
|                              | Lauren Q Wells        |                 |

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-61 and 66-75 is/are pending in the application.
- 4a) Of the above claim(s) 53-61 and 71-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 and 66-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8:15:16</u> . | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

Claims 1-61 and 66-75 are pending. The Amendment filed 3/20/03, Paper No. 11, amended page 7 of the specification and amended claims 1, 28-29, 32, 36-38, 40-42, and 48-52. Claims 53-61 and 71-75 are withdrawn from consideration, as they are directed toward non-elected subject matter.

Applicant's arguments with respect to claims 1-52 and 66-70 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the IDS filed 8/7/02, Applicant argues, "Applicants hereby stipulate that the ICI Companies Datasheet listed on PTO-1449 form and submitted with the above-indicated IDS was dated prior to the filing date of the present application. . . Applicants respectfully request that the Examiner consider this IDS in its entirety and return a copy of the 1449 form previously submitted . . . marked as being considered and initialed by the Examiner". This argument is not persuasive. The Examiner respectfully directs Applicant to MPEP 609 and 37 CFR 1.98(b)(5), which states, "Each publication listed in an IDS must be identified by published, author, title, relevant pages of the publication, date, and place of publication". Thus, until a date is provided, the reference will not be considered.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/6/03 has been entered.

***Claim Warning***

Applicant is advised that should claims 28, 29, 32 and 67 be found allowable, claims 36, 37, 28, 40, 41, 42, 48, 49, 50, 51, 52 and 68-70, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-52, 66-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrases “alkyl-Y containing side chain has at least 4 carbon atoms on average” and “wherein the alkyl group of the alkoxy-containing side chain has 4 to 50 carbon atoms on average”, in claims 1, 28, 36, 38, 40, 42, 48, 50, 51, is vague and indefinite, as the metes and bounds of this claim are unascertainable. Applicant argues, “The alkyl groups of the side chains of each individual monomer in the polymer may be of varying length, but the average number of carbon atoms on the side chain of the monomers that form the polymer is at least 4”. This argument is not persuasive. The phrase “on average” is vague and indefinite, as the metes and bounds of the claim are unascertainable. Does on average mean that it contains 1 carbon atoms?

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The phrase "on average" is vague and indefinite. Deleting this phrase will overcome this rejection.

(ii) The phrase "sparingly soluble" in claims 1, 28, 29, 32, 37, 38, 40, 41, 42, 48, 49, 50, 51, 52, is vague and indefinite, as the metes and bounds of the claims are unascertainable. What is sparingly soluble? Is it 1% soluble? Is it 49% soluble? What does "sparingly" mean? The specification does not define this term and one of ordinary skill in the art would not be apprised of its meaning.

(iii) The phrase "tissue" in claims 38, 40-41, 68 is vague and indefinite, as it is confusing. Does tissue refer to the paper product or does it refer to an in vivo organ?

(iv) Claim 6 is vague and indefinite, as it is confusing. What is the reduction compared to? Greater than 15% of what?

(v) The phrase "mask for the hair" in claim 44 (line 3) is vague and indefinite, as it is confusing. What is a mask for the hair? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

(vi) The phrase "composition for cushioning sores" in claim 45 (last line) is vague and indefinite, as it is confusing. What is the form of a composition that cushions sores? What is meant by cushioning sores? The specification does not define this phrase and one of ordinary skill in the art would not be apprised of its meaning.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-45, 48-52, 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels (5,389,676) in view of Kernstock et al. (4,552,685).

The instant invention is directed toward a water-in-oil emulsion comprising a vinyl polymer comprising ethylene oxide containing side chains and alkyl-Y-containing side chains, wherein Y is O or NR, wherein R is H or CH<sub>3</sub>, and wherein the alkyl group of the alkyl Y containing side chain has at least 4 carbon atoms on average in a cyclic, branched, or straight chain configuration and optionally includes one or more heteroatoms, an oil phase, and a water phase, wherein the vinyl polymer is insoluble or sparingly soluble in the water phase.

Michaels teaches water-in-oil emulsions comprising amphoteric surfactants. Exemplified as emulsions wherein the oil comprises 20% of the emulsion. Glycerine, ethylene glycol, propylene glycol and others, which are considered humectants, are taught as emulsions aids that increase viscosity and do not deactivate the antiinfective activity of the surfactants. Cellulose gums, glycerin, and gelatin are taught as co-emulsion aids that stabilize the emulsion. Hair and body shampoos are taught as preferred composition forms. Gel forms of the composition are additionally taught. The reference lacks vinyl polymers. See abstract; Col. 2, line 60-line 66; Col. 4, line 31-line 58; Col. 5, line 20-line 40; Col. 10, line 64-Col. 11, line 20.

Kernstock et al. teach thickened amphoteric surfactant solutions that are thickened by a polymer of 15-60% an alpha, beta-ethylenically unsaturated carboxylic acid, such as methacrylic acid, 1-30% of a nonionic chain extender of an alpha, beta-ethylenically unsaturated monomer, such as ethyl acrylate, and 15-80% of a nonionic vinyl surfactant ester. See Col. 2 for monoethylenically unsaturated poly(alkylene oxide)(meth)acrylic monomers of

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the instant invention and for alkyl (meth)acrylate monomers of the instant invention. The nonionic vinyl surfactant ester comprises ethylene oxide-containing side chains of isopropylene oxide groups and at least four ethylene oxide groups. The compositions are taught as useful as shampoos and is imparting a most desirable balance of viscosity and clarity properties to an amphoteric surfactant composition. The copolymer is taught as insoluble in an aqueous liquid. The amount of copolymeric thickener most advantageously employed in preparing thickened amphoteric surfactant compositions will vary depending on the specific copolymer employed and the type and concentration of the amphoteric surfactant. Generally, the copolymers comprise from about 0.01 to about 10% of the composition. While the reference does not specifically state isooctyl acrylate, stearyl methacrylate, and polyethylene oxide, the reference does teach these monomers as possibilities. See Col. 2, line 1-Col. 3, line 15; Col. 4, line 11-line 45. See Col. 6, line 64-Col. 8, line 30. See Col. 9, line 42-line 58.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the copolymer(s) of Kernstock et al. to the composition of Michaels because of the expectation of achieving a shampoo that is effectively thickened while maintaining clarity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify a vinyl polymer comprising isooctyl acrylate, stearyl methacrylate and polyethylene oxide methacrylate because of the expectation of achieving a specific thickening property with a specific amphoteric surfactant. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Thus, discovering the



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optimum or workable monomer combinations with the combinations taught by Kernstock et al. would involve only routine skill.

The combination of references teaches the instant composition, thus the composition of the combined references must be stable, substantive, and must have the property of providing a reducing in skin capacitance of greater than about 15% and as having compatibility with various recited bioactive agents.

Claim 22 is not afforded patentable weight, as the future intended use of a composition claim is not given weight.

Since the vinyl polymer taught by Kernstock et al. is that same as that of the instant invention, the vinyl polymer of Kernstock et al. must have the same HLB values.

The Examiner respectfully points out that the recitation of a moisturizing, tissue antiseptic, personal care, and transdermal drug delivery is not given patentable weight; as a recitation of the intended utility in the preamble does not impart patentability to a known composition. In re Spada, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990).

Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels in view of Kernstock et al. as applied to claims 1-45, 48-52 and 66-70 above, and further in view of Omura et al. (2003/0064046).

Michaels and Kernstock et al. are applied as discussed above. The references lack preferred make-up formulations.

Omura et al. teach cosmetic water-in-oil emulsions. Skin creams, hair creams, liquid foundation, eyeliner, mascara, eyeshadow, and other liquid emulsion or cream products, are taught as cosmetic forms of their water-in-oil emulsions. See [0032].

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of the combined references in the form of a make-up, as taught by Omura et al. because Omura et al. teach such water-in-oil composition forms as interchangeable and because of the expectation of achieving thickened, non-irritating mascaras that increases the fullness of the lashes.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
June 5, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

6/15/03